

May 16, 2006

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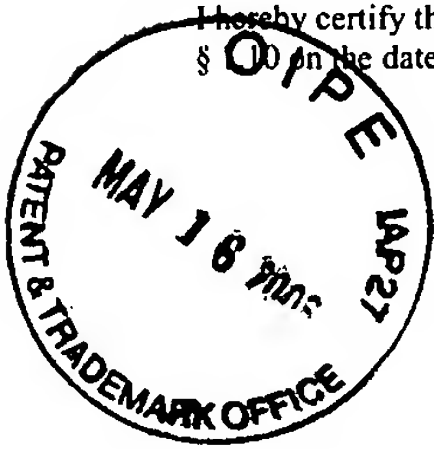
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By: 
Sarah M. Barnett

PATENT

Customer No. 22,852

Attorney Docket No. 07579.0015-01000



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Graham Edmund KELLY (as amended)

Application No.: 10/600,004

Filed: June 18, 2003

**For: METHODS FOR BONE
TREATMENT USING
FORMONONETIN AND OTHER
ISOFLAVONES (as amended)**

Group Art Unit: 1614

Examiner: Cybille DELACROIX-MUIRHEID

Confirmation No.: 6037

Mail Stop RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER
37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents on the enclosed IDS form PTO/SB/08. This Information Disclosure Statement is being filed before the mailing date of a first Office Action after the filing of a Request for Continued Examination in the above-referenced application.

Copies of the listed foreign and non-patent literature documents are enclosed. Copies of the U.S. patent publications are not enclosed.

The United States Court of Appeals for the Federal Circuit held in *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 66 U.S.P.Q.2d 1801 (Fed. Cir. 2003), that an “adverse decision” by another examiner may meet the materiality standard under the amended Rule 56, and thus, Applicant should disclose prior rejections of “substantially similar claim[s]” to the Office. Accordingly, although Applicant is not representing that the Office Actions in the co-pending applications are material to the present application and are not admitting that any of the other claims are substantially similar, out of an abundance of caution, Applicant has listed the substantive Office Actions filed in co-pending applications on the enclosed PTO/SB/08, but copies of those documents are not enclosed because they are available on the USPTO Image File Wrapper System of PAIR.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the enclosed form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute “prior art.” If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute “prior art” under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the claimed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 16, 2006

By: Elisabeth Barek
Elisabeth Jaffe Barek
Reg. No. 46,797

CERTIFICATE UNDER 37 CFR § 1.10 OF MAILING BY "EXPRESS MAIL"

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May 16, 2006

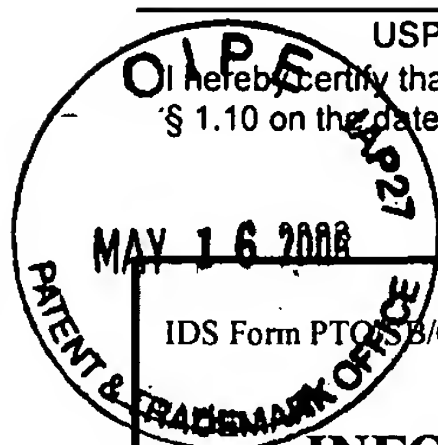
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By: _____

Sarah M. Barnett



IDS Form PTO/SB/08: Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

3

Complete if Known

<i>Application Number</i>	10/600,004
<i>Filing Date</i>	June 18, 2003
<i>First Named Inventor</i>	Kelly
<i>Art Unit</i>	1614
<i>Examiner Name</i>	Delacroix-Muirheid, Cybille
<i>Attorney Docket Number</i>	07579.0015-01000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials*	Cite No.	Document Number Number-Kind Code (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2005/0036962 A1	02-17-2005	Kelly et al.	
		US 2005/0049424 A1	03-03-2005	Kelly et al.	
		US 2005/0059616 A1	03-17-2005	Kelly et al.	
		US 2005/0143588 A1	06-30-2005	Heaton et al.	
		US 5,637,598	06-10-1997	Grese	
		US 6,033,714	03-07-2000	Gugger et al.	
		US 6,987,098 B2	01-17-2006	Kelly	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Country Code Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		EP 0 682 877 B1	04-02-2003	Nichimo Co. Ltd.		
		WO 98/21946 A1	05-28-1998	Internutria, Inc.		
		WO 98/25460 A1	06-18-1998	Zymogenetics, Inc.		
		WO 99/45923 A1	09-16-1999	Merck & Co., Inc.		
		WO 00/16759 A2	03-30-2000	Schnyder		
		WO 00/54753 A2	09-21-2000	Johnson & Johnson Consumer Companies, Inc.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
		"Novogen launches Rimostil," Press Release, 2 pages, http://www.novogen.com/news/newsPopup.cfm?id=22 (June 22, 2000).	
		BABER, R. et al. "The effect of an isoflavone dietary supplement (Rimostil™) on serum lipids, forearm bone density and endometrial thickness in post-menopausal women," <i>10th Annual Meeting of the North American Menopause Society</i> , New York, 4 pages (September 1999).	
		CASWELL, A. (Ed.) "Hypolipidaemic agents," <i>MIMS Annual</i> , 23 rd Edition, pp. 2-152 to 2-168, Tien Wah Press, Singapore (1999).	
		CHANG, Y-C. et al., "Microwave-mediated synthesis of anticarcinogenic isoflavones from soybeans," <i>J Agric Food Chem.</i> 42:1869-1871 (1994).	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/600,004	
			Filing Date	June 18, 2003	
			First Named Inventor	Kelly	
			Art Unit	1614	
			Examiner Name	Delacroix-Muirheid, Cybille	
Sheet	2	of	3	Attorney Docket Number	07579.0015-01000

NON PATENT LITERATURE DOCUMENTS			
		CLIFTON-BLIGH, P. et al., "The effect of isoflavones extracted from red clover (Rimostil™) on lipid and bone metabolism," <i>Menopause</i> 8(4):259-265 (2001).	
		DIXON, R. et al., "Molecular controls for isoflavonoid biosynthesis in relation to plant and human health," <i>Phytochemicals in Human Health Protection, Nutrition and Plant Defense</i> , Kluwer Academic, New York, pp. 133-159 (1999).	
		DÖREN, M. et al., "Identification and treatment of postmenopausal women at risk for the development of osteoporosis," <i>Intl. J. Clin. Pharmacology, Therapy and Toxicology</i> 30(11):431-433 (1992).	
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		GRODSTEIN, F. et al., "Postmenopausal hormone use and cholecystectomy in a large prospective study," <i>Obstet. Gynecol.</i> 83(1):5-11 (1994).	
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		PALMETSHOFER, A. et al., "α-Galactosyl epitope-mediated activation of porcine aortic endothelial cells," <i>Transplantation</i> 65(7):971-978 (1998).	
		PARFITT, K. (Ed.), <i>Martindale, The complete drug reference</i> , 32nd Edition, Pharmaceutical Press, London, Table of Contents, pp. v and vi (1999).	
		PEDERSON, T. et al., "Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S)," <i>The Lancet</i> 344:1383-1389 (1994).	
		SACKS, F. et al., "The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels," <i>The New England Journal of Medicine</i> 335(14):1001-1009 (1996).	
		SBAROUNI, E. et al., "The effect of hormone replacement therapy alone and in combination with simvastatin on plasma lipids of hypercholesterolemic postmenopausal women with coronary artery disease," <i>J. Am. Coll. Cardiol.</i> 32(5): 1244-1250 (1998).	
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IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Application Number</i>	10/600,004
				<i>Filing Date</i>	June 18, 2003
				<i>First Named Inventor</i>	Kelly
				<i>Art Unit</i>	1614
				<i>Examiner Name</i>	Delacroix-Muirheid, Cybille
Sheet	3	of	3	<i>Attorney Docket Number</i>	07579.0015-01000

NON PATENT LITERATURE DOCUMENTS			
		Office Action issued in U.S. Patent No. 6,340,703 on July 9, 1999 (Attorney Docket No. 07579.0006-00000).	
		Office Action issued in U.S. Patent No. 6,340,703 on April 27, 2000 (Attorney Docket No. 07579.0006-00000).	
		Amendment and Response filed in U.S. Patent No. 6,340,703 on October 27, 2000 (Attorney Docket No. 07579.0006-00000).	
		Office Action issued in U.S. Patent No. 6,340,703 on February 9, 2001 (Attorney Docket No. 07579.0006-00000).	
		Amendment filed in U.S. Patent No. 6,340,703 on May 31, 2001 (Attorney Docket No. 07579.0006-00000).	
		Office Action issued in U.S. Patent Application No. 09/986,509 on July 23, 2002 (Attorney Docket No. 07579.0006-01000).	
		Amendment filed in U.S. Patent Application No. 09/986,509 on December 23, 2002 (Attorney Docket No. 07579.0006-01000).	
		Office Action issued in U.S. Patent Application No. 09/986,509 on February 6, 2004 (Attorney Docket No. 07579.0006-01000).	
		Amendment and Response filed in U.S. Patent Application No. 09/986,509 on August 5, 2004 (Attorney Docket No. 07579.0006-01000).	
		Office Action issued in U.S. Patent Application No. 09/986,509 on October 24, 2005 (Attorney Docket No. 07579.0006-01000).	
		Amendment and Response to Office Action filed in U.S. Patent Application No. 09/986,509 on April 24, 2006 (Attorney Docket No. 07579.0006-01000).	
		Office Action issued in U.S. Patent No. 6,599,536 on October 23, 2001 (Attorney Docket No. 07579.0013-00000).	
		Amendment filed in U.S. Patent No. 6,599,536 on March 25, 2002 (Attorney Docket No. 07579.0013-00000).	
		Office Action issued in U.S. Patent No. 6,599,536 on June 18, 2002 (Attorney Docket No. 07579.0013-00000).	
		Amendment and Response After Final filed in U.S. Patent No. 6,599,536 on December 17, 2002 (Attorney Docket No. 07579.0013-00000).	
		Notice of Allowance with Statement of Reasons issued in U.S. Patent No. 6,599,536 on April 8, 2003 (Attorney Docket No. 07579.0013-00000).	
		Preliminary Amendment filed in U.S. Patent Application No. 10/459,537 on June 12, 2003 (Attorney Docket No. 07579.0013-01000).	
		Office Action mailed in U.S. Patent Application No. 10/459,537 on December 20, 2005 (Attorney Docket No. 07579.0013-01000).	
		Office Action mailed in U.S. Patent Application No. 09/914,035 on December 18, 2002 (Attorney Docket No. 07579.0015-00000).	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.